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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/529,449

03/28/2005

Kazuyuki Yamane

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DINSMORE & SHOHL, LLP
1900 CHEMED CENTER
255 EAST FIFTH STREET
CINCINNATI, OH 45202

EXAMINER

TOSCANO, ALICIA

ART UNIT

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1796

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/529,449	Applicant(s) YAMANE ET AL.	
	Examiner Alicia M. Toscano	Art Unit 1796	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 April 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,5,7,10,11,18,23,24,26 and 28-30 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,5,7,10,11,18,23,24,26 and 28-30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Objections

1. Claim 1 is objected to because of the following informalities: claim 1 has the limitation of a chain lengthening ratio of 1.65 to 5.00, a lower limit MW before chain lengthening of 30,000 and a lower limit MW polymer after chain lengthening of 181,000. If one chain lengthens a 30,000 MW polymer to the highest ratio of 5.00 the highest MW obtainable is 150,000 ($30,000 \times 5$). Thusly it appears to the Examiner that a lower MW limit of 30,000 is unable meet the 181,000 limitation of the claims. Appropriate correction/clarification is required.

Claim Rejections - 35 USC § 102

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

2. Claims 1, 5, 7, 10 and 29-31 are rejected under 35 U.S.C. 102(b) as being anticipated by Matsumoto (JP 2001/323056).

Masumoto includes elements as previously set forth in the action dated 6/4/07. Claim 22 is newly cancelled and removed from the rejection. Use of 2 wt% oxazoline is disclosed in Ex 6 of Matsumoto. Additionally, since end product requirements are met (see [0010], a MW of 100,000-300,000 is disclosed), the process required to produce said end product is not pertinent unless applicant shows otherwise. Said MW meets the limitations of the newly amended claim 1 and its dependants. Since the MW weight

and compositional requirements are met the property requirements therein are found inherent. See additional comments below.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. Claims 1, 5, 7, 10, 29, 30 and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shinoda (US 5247013).

The high molecular weight aliphatic polyester of claim 1 is viewed as a product-by-process claim and hence the methods they are created by are not pertinent, unless applicant can show a different product is produced.

Shinoda discloses polyesters formed from glycolic acid (Column 1 line 23) having a MW of 155400 and PDI of 3.7 (Table 2 Ex 11, wherein $MW = M_n \cdot PDI$).

Shinoda does not disclose a product comprising a MW of at least 181,000 as required by the newly amended claims.

Shinoda discloses that the MW is result effective variable. Decreasing the MW increases the rate of hydrolysis and vice versa (Column 3 lines 38-40). Shinoda exemplifies in Table 1, Ex 1-3 that lowering the amount of methyl-glucoside from 20 to 0.018 results in an increase in MW and a decrease in hydrolysis. Ex 11, to which the Examiner referred to above, discloses the use of glycolide with 0.07 wt% methyl-glucoside.

It would have been obvious to one of ordinary skill in the art at the time of the invention to decrease the amount of methyl-glucoside additive during the polymerization of glycolide, as taught by Shinoda, in order to increase the molecular weight and decrease the hydrolysis rate. Given that the PDI of the other examples of glycolide polymerized with an additive are all within the claimed ranges, and that the compositional elements of the claims are met, the Examiner finds the PDI and other properties of the claims to be inherent in the composition of Shinoda.

4. Claims 11, 18, 23, 24, 26 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Matsumoto.

Masumoto includes elements as previously set forth in the action dated 6/4/07. Rejection over claims 17, 25 and 27 is removed since said claims are newly cancelled. The motivation to vary the time of reaction to increase the MW is as set forth previously and as such the MW requirements are deemed met. Matsumoto discloses in Ex 6 the use of 2.02 parts by weight oxazoline, or 2.02 wt%, meeting the new wt% requirements of the above claims. Since the compositional elements and processing conditions are met as previously set forth the properties, chain lengthening, end MW, PDI and (T2-T1) difference therein are found inherent. See additional comments below.

5. Claims 1, 5, 7, 10-11, 18 and 23, 24, 26 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bonsignore in view of Matsumoto.

Bonsignore and Masumoto include elements as previously set forth in the action dated 6/4/07. Rejection over claims 17, 21, 22, 25 and 27 is removed since said claims are newly cancelled. Matsumoto discloses in Ex 6 the use of 2.02 parts by weight oxazoline, or 2.02 wt%, meeting the new wt% requirements of the above claims. Motivation to use a range of 0.5-2 wt% in Bonsignore was set forth in the action dated 6/4/07. Since the compositional elements and processing conditions are met as previously set forth the properties, chain lengthening, end MW, PDI and (T2-T1) difference therein are found inherent. See additional comments below.

Conclusion

Response to Arguments

6. Applicant's arguments filed 4/14/08 have been fully considered but they are not persuasive. Applicant argues that a comparison of Ex 1 and 2 at pgs 22-24 of Applicant's disclosure shows that the claimed properties are not inherent in all reaction products/processes of a ring-opening copolymer. Applicant argues Shinoda does not disclose a MW of 181,000-500,000. Applicant argues that just as identical processes may be presumed to provide identical products, products are generally presumed to be different from each other when their production processes are different. As such Applicant argues that the reaction product of Applicant's disclosure is clearly different than the product exemplified by Ex 3 of Matsumoto in view of the difference in the amount of oxazoline incorporated therein. Applicant argues shorter kneading periods are disclosed by Matsumoto and thusly the polyester is merely terminated with the

oxazoline, not chain lengthened. Applicant argues it is the burden of the Examiner to show that a prior art reference discloses all of the limitations necessary to inherently result in the product claimed, and that the Examiner has failed to do so. Regarding Bosignore Applicant argues Bosignore merely mentions that polyglycolic acid is conventionally prepared by condensation polymerization and that Bosignore does not mention making high molecular weight polyglycolic acid compounds. Applicant argues there is no basis or reasoning to apply any of Bosignore's teachings with respect to lactic acid to glycolic acid. Applicant argues Matsumoto and Bosignore do not disclose the claimed compound.

Examiner disagrees. Applicant has not successfully shown that the products of Shinoda, Masumoto and Bonsignore do not result in the inherent properties. The Examiner can conclude, based on Ex 1 and 2 of Table 1, that when oxazoline is used, 1 wt% of oxazoline is needed to meet the requirements of Applicant's claims. Said limitation is met by the references set forth above. Since the MW of Comp Ex 1 and Comp Ex 2 is not within the claimed range, and since the references above do meet the claimed MW range, Applicant has not successfully shown that the product of the references above would have different properties than that claimed. The Examiner's position of inherency thusly stands. Regarding Shinoda, new grounds of rejection are as set forth above. As such Shinoda does meet the limitations of Applicant's claims and Applicant's arguments drawn to such are found moot. That Matsumoto discloses a different process is found moot since Applicant has not show said process to result in a different product. Applicant continues to argue that the polymer of Matsumoto is merely

chain terminated however Applicant offers no support or evidence other than speculative arguments. Applicant's argument that different products are produced by different processes is not persuasive since said arguments are merely speculative and no qualitative support has been presented. As such the rejections in view of Matsumoto are found proper and stand. The Examiner has put forth that since the required compositional and procedural elements are met the properties therein are deemed inherent. It is unclear to the Examiner what limitations other than said elements are necessary to result in the properties of Applicant's claims. If there is a critical element not claimed which results in the properties the Examiner requests evidence of such, and said element must be put in the claims. The Examiner requests evidence that the properties are not inherent. Regarding Bonsignore, the Examiner put forth clear motivation to replace glycolic acid with lactic acid, i.e. that they are recognized functional equivalents. As such Applicant's arguments that proper motivation was not set forth is found moot. Since the motivation to combine is proper, the claimed compound is met by Matsumoto and Bonsignore. The rejection is proper and stands.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alicia M. Toscano whose telephone number is (571)272-2451. The examiner can normally be reached on M-F 8:00 AM to 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Randy Gulakowski can be reached on 571-272-1302. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1796

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

AMT

/Randy Gulakowski/
Supervisory Patent Examiner, Art Unit 1796